



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In re Application of:

Jerry M. COLLINS et al.

Application No. 10/088,561

Confirmation No.: 6698

Filed: March 19, 2002

For: IMAGING OF DRUG
ACCUMULATION AS A GUIDE
TO ANTITUMOR THERAPY

Art Unit : 1616

Examiner: Dameron JONES

Attorney Docket No. 31978-178825

Customer No:



26694

PATENT TRADEMARK OFFICE

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

In response to the restriction requirement mailed April 28, 2003, Applicants elect Group I, claims 1-24, 28 and 29, wherein the labeled drug is 11C-paclitaxel, with traverse.

Applicants traverse the restriction on several grounds. First, Applicants note that lack of unity of invention was never asserted during the international stage and is thus improper here.

Further, Applicants submit that there is unity of invention and the restriction requirement is improper. The present application is a National Stage application of a PCT International Application. Thus, PCT rules 13.1 and 13.2 apply rather than normal U.S. restriction practice. As set forth in PCT Rule 13, unity of invention is met if the claims refer to a single general inventive concept. In the present application, the single general inventive concept is the use of radiolabeled probes that comprise specific anti-cancer agents having a label incorporated into the

structure without adding additional structural features, and the use of those probes for PET scanning to measure various aspects of drug accumulation and efficacy. Method claims 1-19 are applicable to a wide range of chemical compounds. The restriction requirement asserts that the Group VII claims would require the Examiner to search all possible drugs and the sheer volume of the drugs that could be labeled is too extensive. However, the application is not so broad as to consider any anti-cancer drug. Rather, the application is drawn specifically to compounds which are labeled anti-cancer drugs. Thus, the search would be limited to labeled anti-cancer drugs having no other chemical modifications. Furthermore, the application is drawn to specific uses of those drugs related to PET scanning and the ability to scan drugs. See, for example, page 7, lines 1-8. Thus, unity of invention as defined by PCT Rule 13 exists and the restriction is improper.

Third, the Examiner has not properly set forth the reasoning for asserting a lack of unity of invention. Following normal Patent Office procedure, the Examiner is required to, in addition to listing the different groups of claims, explain why each Group lacks unity with each of the other groups specifically describing the unique special technical feature in each group. See MPEP 1893.03(d). The Examiner has not fulfilled this requirement. Accordingly, Applicants submit that the restriction is improper and all claims should be examined.

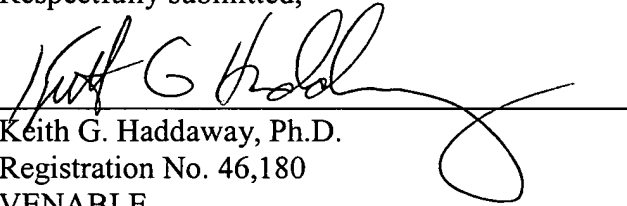
Finally, if there is any division of the application, it should be in the form of an election of species, rather than a restriction. That is, the claims are drawn to a genus of radio-labeled anticancer drugs and uses thereof. The individual drugs recited are, at most, species within that genus and not separate inventions that should be subjected to restriction. For this reason as well, the restriction requirement is improper and should be removed or recast.

Conclusion

Applicants elect Group I, Claims 1-24, 28 and 29 for prosecution, wherein the labeled drug is 11C-paclitaxel, with traverse. It is believed that this response is a complete reply to the restriction requirement and thus Applicants respectfully request that prosecution proceed. Should the Examiner have any questions, which might be amenable to a telephone interview, the Examiner is invited to contact undersigned counsel to discuss such issues. If any fee is required in conjunction with this response, the Commissioner is authorized to charge our deposit account No. 22-0261, and notify undersigned counsel accordingly.

Date: May 28, 2003

Respectfully submitted,



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